procedure and the use of DESs. Long-term follow up with larger population will be necessary to get the clear conclusion.

TCT-195

Quality Of Life After Percutaneous Coronary Interventions: COURAGE Results Apply to the Real World?

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BACKGROUND: The results of the COURAGE study have been questioned, because of the inclusion of a highly selected population. We compared the quality of life (QOL) of patients seen in daily clinical practice with those of the COURAGE study.
METHODS: Prospective observational study of patients with stable angina undergoing PCI at a referral center. The clinical and angiographic characteristics were evaluated, and the Seattle Angina Questionnaire (SAQ) was applied before the procedure and after 6 and 12 months. The data were compared with those reported in the COURAGE study (NEJM 2008;359:677). The t test, chi-square test and multivariate analysis were used.
RESULTS: The study included 110 patients from September 2006 to May 2007. When compared to the COURAGE study, our sample had a higher percentage of women (38% vs 15%), hypertension (82% vs 66%) and prior PCI (29% vs 15%) ($p < 0.001$). Our patients had significantly lower rates of baseline QoL than those in the COURAGE (30 ± 22 vs 51 ± 25, $p < 0.001$), with higher improvement in 12 months (83 ± 22 vs 76 ± 21, $p = 0.002$). The mean change in SAQ was 53 ± 20 in our study versus 25 ± 12 in the COURAGE ($p<0,01$). By multivariate analysis, regular or poor QOL before the procedure was the main predictor of improvement of QOL at 6 months in both studies.
CONCLUSIONS: Our patients presented a profile of greater severity and worse QOL before PCI than those of the COURAGE trial, with more marked improvement in the follow-up. As the baseline QOL is the main predictor of improvement of this index, these results suggest that the COURAGE results may underestimate the benefit of PCI in daily clinical practice.

POSTER

Carotid Disease

(Abstract Nos 196-206)

TCT-196

Carotid Sinus Reactions During Carotid Artery Stenting

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Background: Hypotension and bradycardia frequently occur during carotid artery stenting (CAS) that involves the carotid bulb. To determine the influence of carotid sinus reactions (CSR) on outcomes during CAS we retrospectively reviewed in a prospectively collected database of 861 CAS procedures at our institution.
Methods: Of 861 consecutive CAS procedures, 683 (79.3%) had stenting involving the carotid bulb and were included in this study. All pts were enrolled in various Institutional Review Board Clinical trials. Of those 683 study pts, 406 (59.4%) had CSR, which was categorized by severity: Group 1) minor hypotension and/or bradycardia (n=144); Group 2) prolonged hypotension and/or bradycardia requiring the use of vasopressors (n=198); Group 3) prolonged hypotension and/or bradycardia with transient loss of contralateral hand grip (n=19); Group 4) asystole (>6 sec) with hypotension requiring vasopressors (n=38); and Group 5) CVA with hypotension and/or bradycardia (n=7). CSR pts were then compared to a control group of the 277 pts who had CAS in the carotid bulb and did not have CSR. Continuous variables were expressed as means ± SD, and categorical variables as percentages. Univariate analyses were assessed by two sample Student's t-tests for continuous variables and by Pearson's chi-square analysis for categorical variables. Multivariate stepwise logistic regression analysis was performed to identify independent predictors of CSR. A p-value of <0.05 was considered statistically significant.
Results: Of the 683 patients studied, 344 underwent right CAS and 339 underwent left CAS. There were no differences between the groups with respect to age, symptoms, co-morbidities, or lesion morphology and CSR. Most significant was the correlation between CSR related asystole and right sided CAS vs. left (9.8% vs. 1.1%, $p<0.001$). In addition, contralateral carotid occlusion or bilateral (≥70%) carotid artery stenosis ($p<0.05$), and history of smoking ($p=0.01$) and female gender ($p<0.05$) were independent risk factors for asystole and CVA.
Conclusion: CSR occurred in nearly 60% of the study population. The rate of neurological complications, however, did not significantly increase. It appears, at least in this study that the right carotid baroreceptor is far more sensitive than the left carotid and is an independent risk factor for asystole during CAS especially in the presence of a compromised contralateral carotid artery, history of smoking and female gender.

TCT-197

IIb/IIIa Inhibition In Carotid Artery Stenting Eliminates the Effect Of Age On Stroke Risk

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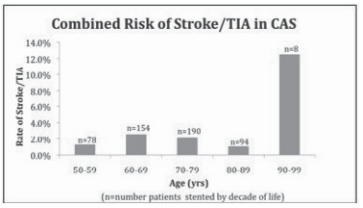
Background: Stroke risk with carotid artery stenting (CAS) increases with age (CREST). IIb/IIIa inhibition with CAS may negate this risk. We report the largest single center experience with IIb/IIIa use in CAS and show no increased risk with age up to 89 years.
Methods: We reviewed 573 consecutive patients who underwent ad-hoc CAS at Baptist Medical Center - Princeton, Birmingham, AL between August, 1999 - August, 2009. Of these, 538 patients were administered a IIb/IIIa inhibitor (eptifibatide, n=536, abciximab, n=2) as adjunctive antiplatelet therapy and this group forms the basis of this report.
Results: The majority of patients (69.5%) were asymptomatic with positive atherosclerotic risk factors of hypertension, coronary artery disease, hyperlipidemia and history of smoking. The overall procedural success rate was 99.3% and an embolic protection device was used in 95.2% of cases. Mean carotid stenosis was 85.6% pre-procedure and 4.8% post-procedure. A total of six strokes and five TIAs were recorded and their distribution by age is shown in Figure 1.
Figure 1. In-hospital Incidence of Combined Stroke and TIA by Age
Patients between the ages of 70-89 had lower rates of combined stroke/TIA than those aged 60-69 years. There was no incidence of stroke (n=1 TIA) in the 90-99 age group.



Conclusions: Periprocedural use of IIb/IIIa inhibition as adjunctive antiplatelet therapy in CAS may eliminate the age-related increased risk of stroke. Whether CAS with adjunctive IIb/IIIa inhibition decreases the stroke/TIA risk compared to carotid endarterectomy (CEA) in elderly patients should be studied in a randomized trial.

TCT-198

Carotid Artery Stenting Versus Medical Therapy: A Meta-analytic Approach to Determine the Best Treatment for High-risk Patients

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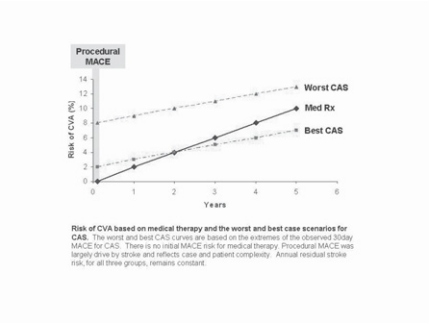
Background: Carotid artery stenting (CAS) is a viable strategy for patients who are high risk for carotid endarterectomy (CEA). The major limitation of CAS is post-procedural stroke. The morbidity of revascularization must be weighed against a conservative medical approach, particularly for patients with limited long-term survival.
Goal: A meta-analytic approach was used to determine the utility of high risk CAS versus medical therapy only for stroke prevention.
Methods: Among 12 high risk CAS registries, the 30-day risk of death, stroke and MI (procedural MACE), ranged from 2-8%. Regardless of the procedural outcome and the patient population, results from SAPPHIRE, CREST, and our institutional database reveal that the subsequent annual risk of ipsilateral stroke is 1.5%/year. The procedural MACE rates were combined with the annual stroke rates to construct curves that represent the stroke risk for the best and worst case scenarios of CAS. These curves were plotted with the results from the 2 major trials of medical therapy, ACAS and ACST, which demonstrated stroke rates of 2% year.
Results: For patients achieving best CAS, stroke outcomes of CAS and medical therapy reach equality after 2 years. At 3 years, CAS is better, but with a NNT of ~100. For worst CAS, the benefits of revascularization will never be realized. Revascularization benefit in high risk patients may be limited by 30% 3-year mortality, which is unrelated to CAS. Thus, patients may not live long enough to offset the early risks of CAS.



Conclusions: The long term benefit of CAS is driven by procedural MACE. The benefit of CAS is only observed when low procedural complication rates can be achieved. Randomized clinical trials are needed to define the utility of revascularization for these patients.

TCT-199

Carotid Angioplasty and Stenting in Octogenarians is as Safe as Surgery

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Purpose: Recent studies, registries (EXACT, CAPTURE) randomized studies (CREST) have shown that carotid angioplasty stenting (CAS) is at higher risk than surgery (CEA) in elderly patients. The aim of this study was to evaluate if CAS performed in octogenarians is as safe as surgery with better indications, choice of the devices, experienced operators..
Methods: 1004 patients (male 733) mean age 70.9 ± 9.4 years underwent 1064 CAS for de novo lesions (n=982) restenoses (n=56) post radiation (n=14) inflammatory arteritis (n=10) post trauma aneurysms (n=2). Indications for treatment: symptomatic carotid stenosis > 70 % (63%) or asymptomatic stenosis > 80 %. Patients were separated into 2 age groups: > 80 y (144 patients, 147 CAS) and <80 y (860 patients, 917 CAS). 188 CAS performed without protection (N.P-) 6 in patients >80 y, 876 with protection (NP+) (occlusion balloon: 334, filters: 537, reversal flow: 6) 141 in patients >80y. Data analysis included neurological complications, death and myocardial infarction (MI) rate at 30 days,

anatomical particularities. Technical points will be described depending on the age of the patient.
Results:Technical success
< 80 years: 915/917
>80 years: 146/147
-30 day outcomes

1064 PROCEDURES	TOTAL	> 80 Y. WITHOUT EPD	WITH EPD	TOTAL	< 80 Y. WITHOUT EPD	WITH EPD
NBR	147	6	141	917	182	735
T.I.A.	2 (1,3%)	1 (17%)	1 (0,7%)	10 (1,1%)	3 (1,6%)	7 (1%)
MINOR STROKE	1 (0,7%)	1 (17%)	0	6 (0,7%)	3 (1,6%)	3 (0,4%)
MAJOR STROKE	0	0	0	3 (0,3%)	2 (1,1%)	1 (0,1%)
RETINAL EMBOLUS	0	0	0	4 (0,4%)	0	4 (0,5%)
HYPERPERFUSION SYNDROME	0	0	0	3 (0,3%)	0	3 (0,4%)
DEATH FATAL STROKE NON FATAL STROKE	0	0	0	5 (0,5%) 4 (0,4%) 1 (0,1%)	2 (1,1%) 2 (1,1%) 0	3 (0,4%) 2 (0,3%) 1 (0,1%)
MI	0	0	0	1 (0.1%)	0	1 (0.1%)
DEATH / STROKE	1 (0,7%)	1 (17%)	0	14 (1,5%)	7 (3,8%)	7 (1%)
DEATH / STROKE / M.I.	1 (0,7%)	1 (17%)	0	15 (1,6%)	7 (3,8%)	8 (1,1%)

EPD: EMBOLIC PROTECTION DEVICES
Conclusion: CAS can be performed in elderly patients without higher risk than in younger patients. But good indications, a meticulous technique, protection devices are mandatory and some technical points must be pointed out to avoid neurological complications and failures.

TCT-200

Facilitating Access to the Supraortic Vessels During Carotid Artery Stenting: Preliminary Clinical Experience With a New Device and Technique

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Background: Carotid artery stenting (CAS) has emerged as a viable option for the treatment of carotid artery disease especially in surgically high risk patients.
Complex supraortic anatomy can make aortic arch branches access both difficult and time consuming and, exposes the patient to prolonged X-Ray exposure and increased contrast medium, exposes the vessels to repeated mechanical stress and the patient to embolic complications risk.
Method: From January 2008 to December 2009, 202 patients with carotid artery disease were treated with CAS. Patient selection was based on high surgical risk; difficult aortic arch anatomy (38% arch type III, 12% bovine arch), risk factors such as neurological symptoms (62%) , advanced age > 75 (54%) and age > 80 (26.7%), supraortic vessels calcification (15%). A homemade modified (pierced) guiding catheter (p-GC) was used. The p-GC is the 7 F MPC guiding catheter (Cordis; Miami, FL) with a manually created hole close to the tip, allowing the passage of a second (anchoring) 0.035" guidewire. This second guidewire stabilizes the overall system, improving control for precise positioning, orientation, access and advancement of the primary guidewire.
Results: Technical access to the target vessel (innominate artery 48.5%) was successful in all but 3 cases (technical success 98.5%) and uneventful in all but 1 case, where a minor stroke occurred (procedural success 99.5%). Although access duration, fluoroscopic time and amount of contrast medium were not systematically measured, a remarkable and unquestionable reduction in all three variables was observed with an access duration well below 20 minutes. Twenty-four (12%) of the patients were considered unsuitable for standard CAS, based on anatomical and clinical risk factors, but were included in this series.
Conclusions: The p-GC has the potential to broaden the inclusion criteria for CAS to patients with anatomical complexity, currently considered at high risk. The preliminary technical and procedural success rates are promising. Product development and further studies are advised.

TCT-201

Largest Single Operator Series Of IIb/IIIa Inhibition with Carotid Artery Stenting

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Background: IIb/IIIa inhibitors are contraindicated in carotid artery stenting (CAS) due to reports of increased bleeding, particularly intracerebral hemorrhage (ICH). We report safety data in the largest series to date of adjunctive IIb/IIIa inhibitor use in CAS.
Methods: We reviewed 573 consecutive patients who underwent ad-hoc CAS at Baptist Medical Center - Princeton, Birmingham, AL from August, 1999 - August, 2009. Of these, 538 patients were administered a IIb/IIIa inhibitor (eptifibatide, n=536, abciximab, n=2) as an adjunct to standard antiplatelet therapy of 325mg aspirin and 600mg clopidogrel. IIb/IIIa inhibition was administered as a single bolus in all but a few (n=7) cases. Patients received bivalirudin or heparin as the primary anticoagulant during the procedure. Hematologic testing and a neurological exam were performed pre and post intervention. A stat CT brain scan and independent neurological consult were obtained for patients with peri-procedural neurological symptoms, including headache.
Results: The majority of patients were asymptomatic (69.5%) with atherosclerotic risk factors of: hypertension, coronary artery disease, hyperlipidemia and history of smoking. The overall procedural success rate was 99.3% and an embolic protection device was used in 95.2% of cases. Mean stenosis of the carotid lesion was 85.6% pre-procedure and 4.8% post-procedure. There was one (0.2%) case of ICH in a 70-year-old male with 99.9% symptomatic right ICA stenosis. In this patient, anti-thrombotic therapy consisted of aspirin, clopidogrel, bivalirudin and adjunctive use of a single bolus of eptifibatide. The patient developed altered consciousness 30 minutes post-procedure and CT showed a large ipsilateral ICH. Other complications in the series included death (0.9%), ischemic stroke (1.1%), TIA (0.9%) and access site bleeding (3.0%). Two of the total 5 deaths were from complications post-CABG.
Conclusions: Adjunctive use of the IIb/IIIa inhibitor eptifibatide is safe. This approach provides a strategy for ad-hoc carotid intervention where loading with oral anti-platelet therapy days before CAS is not necessary.

TCT-202

A Novel Method To Reduce The Risk Of Post-CAS Stroke In The Elderly

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Introduction: The incidence of strokes , usually minor , is significantly higher after CAS than CEA , especially in the elderly patients due to challenging anatomy and difficult carotid access. We propose a facilitated access to the carotid artery , that in an observational serie reduced the percentage of minor strokes .
Methods: From Jan 2002 till Mar 2010 , we performed 180 CAS in patients with type II b & III aortic arches , mean age 78 +- 10 years . In the first group (75 patients) , we used the Exchange technique & in the second group (105 patients) , we used dedicated guiding catheters (SAAD guidings- Cordis) allowing rapid & direct one step access to the carotid artery . There were no significant differences between the 2 groups. In particular , 35% had experienced previous TIAs or stroke . The primary endpoint of this controlled serie was ipsilateral ischaemic stroke or death in the per-procedural period & at 30 days , as evaluated clinically by an independent neurologist.
Findings: In the first group (75patients) , with the Exchange technique , 7 minor ishaemic strokes were recorded & 1 death from hemorrhagic stroke at day 5 ; in the second group (105patients) , using the one step guiding access , no ishaemic stroke was reported , but there were 2 deaths from cardiac causes (respectively chi square <0.04 & ns).
Conclusion: In our hands , the use of dedicated guiding catheters (SAAD guidings - Cordis) allowed rapid & safe access in challenging carotid anatomy reducing dramatically the incidence of post stenting strokes .

TCT-203

Carotid Angioplasty and Stenting under Protection is Becoming the Gold Standard Treatment of a Carotid Stenosis in High and Low Risk Patients

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Background: Carotid Angioplasty and Stenting (C.A.S.) is a new alternative treatment for a carotid artery stenosis. Cerebral protection devices (CPD) should be routinely used to reduce neurological complications. Recent studies have shown that C.A.S. has superior short-term outcomes than Carotid Endarterectomy (C.E.A.) in high surgical risk patients (H.R.). It is not clear however, whether low surgical risk patients (L.R.) are also at lower risk. We compared short term outcomes of C.A.S. in H.R. and LR. patients.
Methods: We analyzed all C.A.S. performed under CPD. HR factors included age >80 yrs, post surgical restenosis, prior neck surgery or radiation, contralateral occlusion, low or high anatomic lesion, unstable or severe coronary or heart diseases, severe commorbidities.
Results: In our series of 1064 C.A.S (1004 pts), 876 performed under CPD in 831 patients (M: 630). mean age: 70.9 ± 9.6 y, using occlusion balloon (n=334), filters (n=537), and reversal flow technique (n=6). 551 were at HR, 325 (65%) at LR, symptomatic 63%. HR and LR pts had similar success rate of EPD deployment (99%), and stent placement (100%).
No statistical difference between occlusion balloon and filter for 30-day death and stroke rate, embolic events (0.3% vs 0.6%, p=n.s) (1,4% vs 1.7%, p=n.s). No difference between symptomatic (HR: 1.1%, LR: 0.5%) and asymptomatic pts (HR: 0.5%, LR: 0.7%) (P=NS)
30 day outcomes

	HIGH RISK n = 551	LOW RISK N=325	Table of Contents P value T.I.A N.S P value
T.I.A	5 0,9%	3 0,9%	N.S
MINOR STROKE	3 0,5%	0	N.S
MAJOR STROKE	1 0,2%	0	N.S
RETINAL EMBOLUS	2 0,4%	2 0,6 %	N.S
HYPERPERFUSION SYNDROME	2 0,4%	1 0,3%	N.S
DEATH FATAL STROKE NON STROKE DEATH	2 0,4% 2 0,4%	1 0,3% 1 0,3%	N.S N.S N.S
DEATH AND STROKE	6 1,1%	1 0,3%	N.S
M.I.	1 0,2%	0	N.S
EMBOLIC EVENTS	11 2%	5 1,5%	N.S

Conclusion: C.A.S under protection is safe with favorable low event rate in HR and LR patients. LR patients have a trend toward lower death and stroke rate after C.A.S compared to C.E.A., but it is not statistically significant. C.A.S should be enlarged to L.R patients. C.A.S is becoming the gold standard treatment of a carotid stenosis.

TCT-204

A New Modular Embolic Protection System: European Experience

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Background: Higher success rate of embolic protection in Carotid Artery Stenting (CAS) procedures has shown recently to reduce periprocedural rate of major adverse cardiac and cerebrovascular events (MACCE). We present the European experience in patients undergoing CAS using a novel modular guidewire-independent distal filter.
Methods and Results: The GARDEX Embolic Protection System (Gardia Medical Ltd., Israel) is a rapid exchange pre-crimped distal filter system used with 0.014" guide wire according to physician preference. It is a stent like system in form and operation. The GARDEX system is deployed after a 0.014" guidewire of choice was positioned across the lesion in a standard fashion. Than the GARDEX stand-alone filter unit can be delivered, positioned and locked anywhere along the guide wire, resulting

POSTER